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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/375,169	08/16/1999	CAROLYN R. AITA	26767-1000	4691

25213 7590 08/02/2002

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EXAMINER

MCNEIL, JENNIFER C

ART UNIT	PAPER NUMBER
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1775

DATE MAILED: 08/02/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/375,169

Applicant(s)

AITA ET AL.

Examiner

Jennifer McNeil

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-16, 18, 19, 21-28, 30,31,33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-27 is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,11-13,16,18,19,28,30,31 and 33 is/are rejected.
- 7) ☒ Claim(s) 9,10,14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 5, 2002 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 16, 19, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "claim 5" in line 1. There is insufficient antecedent basis for this limitation in the claim. For the purposes of examination, it is considered to depend from claim 1.

Claim 16 refers to the outer component having a thickness of "about 1 to about 100 nm". However, the independent claim 1 recites that the outer component has at least one layer "less than 100 nm". The range of "about 100" is not consistent with the range "less than 100". Please correct the ranges claimed.

Claim 19 refers to the outer coating comprising an aluminum compound. However, the independent claim 18 recites that the outer coating is selected from the group consisting of AlN, ZrN, and HfN. Does applicant intend claim 19 to include AlN as the outer coating. Please clarify.

Claim 30 recites the limitation "the aluminum compound" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 8, 12, 13, 16, 18, 19, 28, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aita et al (US 5,472,795) in view of Davidson (US 5,782,910). Aita et al teach a multilayer nanolaminate containing polycrystalline zirconia. The substrate or support (11) may be of any desired material including glass or plastic. Thin layers of zirconia are alternated with layers of a hard ceramic material. Two or more layers are preferably alternately coated onto the support. A multiplicity of these layers would serve as bilayers. The hard ceramic may be made of materials such as oxides, nitrides, and carbide (col. 2, lines 61-67; col. 3, lines 1-24), and these ceramic layers have a thickness in the range of 3 nm to about 1 micron (col. 5, lines 35-51). Aita et al do not give specific examples of additional hard ceramics other than alumina, silicon carbide, boron nitride, or titanium nitride. Davidson '910 teaches an implant having coatings of hard ceramics. These hard ceramics include titanium nitride, titanium oxide, zirconium oxide, zirconium nitride, and zirconium or titanium carbide (col. 6, lines 38-54). As it is taught by Davidson that hard ceramic coatings such as titanium nitride and zirconium nitride are equivalents, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the hard ceramic ZrN for the hard ceramic TiN in the invention of Aita et al.

Regarding claim 7, the inner coating of zirconia may be less than 6nm thick (col. 4, lines 56-67).

Regarding claim 4, the same of the prior art is considered to possess the same characteristics.

Regarding claim 12, 6 nm is considered to meet the limitation "up to about 1 micron".

Regarding claim 19, it would have been obvious to one of ordinary skill in the art at the time to use any material known in the art which is hard and biocompatible.

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Claims 1, 3, 4, 11, 12, 16, 28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,649,951) in view of Davidas (US 4,326,305). Davidson '951 teaches zirconium oxide and zirconium nitride coated stents. The stent body comprises a metal selected from zirconium or zirconium-containing alloys that are coated with a corrosion resistant ceramic such as ZrO or ZrN. This coating may then be coated by another hard, biocompatible coating. Davidson does not give specific examples of what this hard, biocompatible coating may comprise. Davidas teaches implants in which a metallic body is coated with a biocompatible material that is also insulative and has a thickness of 100 angstroms to 0.5 microns, such as AlN. As it is taught by Davidas that AlN is a biocompatible material which provides insulation for implants, it would have been obvious to one of ordinary skill in the art to use AlN as the additional biocompatible coating in the article of Davidson '951, to provide a coating which is compatible in the body, as well as provides insulation to the article.

Claims 1, 3, 4, 11, 12, 16, 28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davidson (US 5,649,951) in view of Davidson (US 5,782,910). Davidson '951 teaches zirconium oxide and zirconium nitride coated stents. The stent body comprises a metal selected from zirconium or zirconium-containing alloys that are coated with a corrosion resistant ceramic such as ZrO or ZrN. This coating may then be coated by another hard, biocompatible coating and will have improved attachment strength due to a closer hardness match (col. 6, line 64- col. 7, line 7). Davidson does not give specific examples of what this hard, biocompatible coating may comprise. Davidson '910 teaches a cardiovascular implant with a base of a zirconium alloy and having coatings of hard ceramics. These hard ceramics include titanium nitride, titanium oxide, zirconium oxide, zirconium nitride, and zirconium or titanium carbide (col. 6, lines 38-54). As it is taught by Davidson '910 that hard ceramic coatings such as titanium nitride and zirconium nitride may be provided on cardiovascular implants such as stents, it would have been obvious to one of ordinary skill in the art at the time of the invention to use one of these coatings as the hard ceramic coating of Davidson '951.

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Allowable Subject Matter

Claims 9, 10, 14, and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21-27 are allowed.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 7, 8, 11-13, 16, 18, 19, 28, 30, 31, and 33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer McNeil whose telephone number is 703-305-0553. The examiner can normally be reached on Monday through Friday, 9:30AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones can be reached on 703-308-3822. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer McNeil
Examiner
Art Unit 1775

JCM
July 27, 2002


DEBORAH JONES
SUPERVISORY PATENT EXAMINER